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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 7 March 2003 with an application for Letters Patent number 524638 made by HOWMEDICA OSTEONICS CORPORATION.

Dated 16 March 2004.

Neville Harris

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
NEW ZEALAND

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NEW ZEALAND

PATENTS ACT 1953

PROVISIONAL SPECIFICATION

"Illuminable Retractor"

We, **HOWMEDICA OSTEONICS CORP.**, a corporation incorporated under the laws of the State of ....., of 59 Route 17 South, Allendale, New Jersey 07401, The United States of America do hereby declare this invention to be described in the following statement:

The present invention relates to a retractor useful for minimally invasive and minimal incision hip surgery.

With surgery of the kind referred to above (whether for hip replacement or other purposes) there is a need for a retractor. Unfortunately with such a retractor and its size relativity to the incision there is a negation of the effectiveness of any overhead lighting.

Therefore for this purpose we believe a source of light (preferably of very low profile) associated with the retractor will better allow vision of the distal end regions of the retractor.

Various retractors have been proposed. See for example, US Patents 5,928,139 and 6,139,493 and PCT Publication WO 02/19919.

The present invention however recognises a need for a retractor (suitable for such hip surgery) [whether an anterior retractor or otherwise] preferably of low profile yet having an illuminable distal retraction end linked to a handle capable of being manipulated during surgery.

In a first aspect the invention consists in **a retractor assembly** suitable for hip or other joint surgery, the assembly comprising or including

a structural member capable of being used as a retractor, the structural member having, as a proximal region, a handle or manipulation control region ("handle") extending through a curved region to a distal region adapted for use in a suitable patient,

a light ducting member or assembly of members ("*light ducting means*") at least in part in substantial conformity to the curved region adapted (with respect to the structural member with a light inlet nearer the proximal region than the distal region) in use to receive (preferably ducted) light and reliant on internal reflection of the light, to transmit such received light about at least part of the curved region to an emission outlet or outlets ("light outlet") which will cast light to a zone at and/or about said distal region, and

a shield overlying at least that part of the light ducting means in substantial conformity to at least part of the curved region,

wherein the light ducting member, the shield and the structural member can be brought into assembly so that directly and/or indirectly each of the light ducting member and the shield is in a supported condition relative to the structural member.

As used herein "curved" in respect of the "curved region" can mean any appropriate angular transition from one end to the other end thereof whether regular or irregular and whether continuous or intermittent or otherwise.

As used herein "supported condition" means supported against accidental easy skewing or separation.

As used herein the term "and/or" has the meaning "and" or "or" and, where the context might allow, both.

As used herein "(s)" at the end of a word means either or both the singular and plural forms of the word.

Preferably the supported condition provides directly and/or indirectly a support of both a proximal and distal region of the ducting member and/or both a proximal and distal region of the shield.

In some forms of the present invention indirect support for the light ducting member might be provided by a direct support by the structural member of the shield which by overlying the light ducting member thus provides support therefore relative to the structural member.

In some forms such direct and/or indirect support can involve the light ducting means, whether as a member or an assembly of members, being engageable to the structural member by any appropriate means at or adjacent a distal region of the light ducting means. Examples include a clip-fit arrangement, a slide on arrangement or any alternative.

Options of such direct or indirect engagement of a light ducting member to the structural member, the shield to the structural member and the light ducting member to the shield are disclosed hereinafter and all such forms of relationship and any combination of them falls within the scope of the present invention.

Preferably the light ducting means at least from its light inlet to its light outlet is a moulded member (of one or more material(s)) having a surface adapted to internally reflect light so as to favour ducting of light from the inlet to the outlet.

Preferably the outlet is an outlet that issues as a beam or beams a band of light rather than a more consolidated area of light, e.g.; preferably the light inlet is adapted to receive light from a fibre optic bundle, a light cable or the like and may be, for example, of a circular area whilst the surfaces surrounding the light path from the inlet to the light outlet is such as to duct the light to the more banded form light outlet.

Preferably any such banded outlet conforms more to the transverse extent of the structural member at, at least the more distal part of the curved region.

Preferably the curved region has a major transverse axis of the structural member normal to the curving thereby to provide a low profile for the curve region.

As used herein the term "low profile" refers to a retractor or retractor assembly or components thereof better able to provide less of a profile transversely down through the

curved region than it provides in other directions, i.e.; substantially as hereinafter described by reference to preferred embodiments.

Preferably the light ducting means is an assembly of a moulded plastics component having the light inlet and the light outlet(s) and a means of association thereof (e.g.; attachment apparatus as hereinafter referred to) to the structural member.

In another aspect the invention consists in **a retractor assembly** suitable for hip or other joint surgery, the assembly comprising or including

a structural member capable of being used as a retractor, the structural member having, as a proximal region, a handle or manipulation control region ("handle") extending through a curved region to a distal region adapted for use in a suitable patient,

a light ducting member or assembly of members ("*light ducting means*") at least in part in substantial conformity to the curved region adapted (with respect to the structural member with a light inlet nearer the proximal region than the distal region) in use to receive (preferably ducted) light and reliant on internal reflection of the light, to transmit such received light about at least part of the curved region to an emission zone ("light outlet") which will cast light to a zone at and/or about said distal region, and

a shield overlying at least that part of the light ducting means in substantial conformity to at least part of the curved region,

wherein the light ducting member, the shield and the structural member can be brought into assembly so that directly and/or indirectly each of the light ducting member and the shield is in a supported condition relative to the structural member.

In a further aspect the invention consists in **a structural member** of a retractor assembly as aforesaid.

In a further aspect the present invention consists in **light ducting means** (as defined previously) as aforesaid.

In yet a further aspect the present invention consists in **a shield** suitable for a retractor assembly as aforesaid.

In a further aspect the invention is a **sterile light ducting means** as aforesaid in a pack therefor.

In a further aspect the present invention consists in, **in combination**, as a sterile pack, light ducting means and a shield as aforesaid.

In a further aspect the present invention consists in **a method of providing a retractor assembly** as aforesaid, said method comprising or including taking a light ducting means (and

preferably also a shield) from a pack and associating the same with the structural member and the shield.

Preferably the structural member is sterile prior to such association of the light ducting means and shield therewith.

Preferably the light ducting means and optionally also the shield is disposable.

In another aspect the present invention consists in **a retractor useful in surgery (e.g.; hip surgery)**, said retractor having

a main structural element defining

a handle region,

a distal region, and

an intermediate region, said intermediate region curving on planes normal to its main transverse dimension thereby to define a low profile form having a "concave" lower side and a "convex" upper side,

a light duct capable of ducting light it receives, said duct, at least in part away from its handle proximate inlet end, substantially conforming to the intermediate region so as to maintain a low profile thereover whilst having an emission end capable of emitting light the duct has received towards a zone in which said distal region of the main structural element is being operated,

attachment apparatus integral with or attaching to the light duct at or adjacent the inlet end of the light duct engaged with or for engagement with the main structural member, and

a shielding member attachable to at least one of

i) the attachment member,

ii) the light duct, and

iii) the intermediate member

so as, also in a low profile at least in part away from its handle proximate end, of substantially conforming to the light duct and/or the adjacent intermediate region.

As used herein the terms "convex" and "concave" are not used in any strict geometrical sense but rather as a means of conveying a continuous or discontinuous curving or some variation thereof where there is some degree of surface to surface concordance better to provide a low profile whilst ensuring the angular offset needed for retraction use.

Preferably the light duct is a moulded transparent plastics member preferably having the attachment integrally moulded therewith. Alternatively preferably the light duct is a fabrication from two moulded components.

Preferably said light duct is adapted at its inlet end to receive light ducted via light cable, a fibre optic bundle, tube, light cable or the like.

Preferably the ratio between the light inlet surface area and light outlet surface area is a ratio of no less than 1:1 and no more than 1:11 The current preferred designed ratio is 1:2.2

Preferably the emission end of the light duct is substantially of a flattened section so as to better conform to the low profile of the intermediate region.

Preferably the ratio between the light inlet surface area and light outlet surface area is a ratio of no less than 1:1 and no more than 1:11 The current preferred designed ratio is 1:2.2

Preferably the flattening and broadening is such that the outlet is thinner than the inlet diameter or notional diameter and is at least as wide as two such diameter (preferably is three or more such diameters in width).

Preferably the light duct splays to said flattened form from a non flattened form at the inlet end.

Preferably said shielding member has a form adapted to conform closely to the flattened form of the light duct.

Preferably said main structural element, light duct, attachment apparatus and/or shielding member is substantially as hereinafter described with reference to any one or more of the accompanying drawings.

In another aspect the invention consists in **a retractor assembly** suitable for hip or other joint surgery, the assembly comprising or including

a structural member capable of being used as a retractor, the structural member having, as a proximal region, a handle or manipulation control region ("handle") extending through a curved region to a distal region adapted for use in a suitable patient, and

a light ducting member or assembly of members ("*light ducting means*") at least in part in substantial conformity to the curved region adapted (with respect to the structural member with a light inlet nearer the proximal region than the distal region) in use to receive (preferably ducted) light and reliant on internal reflection of the light, to transmit such received light about at least part of the curved region to an emission outlet or outlets ("light outlet") which will cast light to a zone at and/or about said distal region, and

wherein the light ducting member and the structural member can be brought into assembly so that the light ducting member and the shield is in a supported condition relative to the structural member.

In still a further aspect the present invention consists in a **retractor** in accordance with the present invention useful in hip surgery, said retractor capable of being assembled and

disassembled by attachment and removal respectively of components. In some forms some of the components can be disposable but preferably each is capable of being cleaned for reuse.

In still a further aspect the present invention consists in **the use of a retractor assembly or retractor** in accordance with the present invention, the inlet end of the light transmitter receiving a feed of light to illuminate a zone in which the distal region of the main structural element is being operated.

In still a further aspect the present invention consists **in a method of treating a mammalian patient** (whether a human being or otherwise) which involves the operative use of a retractor assembly or retractor of the present invention as a retractor.

Preferably said method involves feeding light into the light transmitter or duct thereby to illuminate part of the patient (e.g.; during a hip replacement operation).

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

A preferred form of the present invention will now be described with reference to the accompanying drawings in which

Figure 1 shows a partial sub-assembly of an anterior retractor suitable for use in hip replacement operations, the sub-assembly showing attached by a clip or attachment apparatus a light duct (preferably of solid transparent material) spreading to a low profile form (i.e.; from its handle proximate light inlet end to its beam directing outlet end) adapted to bathe a zone adjacent the distal region shown in a band of light or light beams, the shield being shown exploded off the assembly but showing how that too maintains a low profile over the regions of the assembly likely to be in or close to being in a patient during the course of an operation,

Figure 2 shows various views of a light duct or pipe (but of solid material so as to "pipe" by internal reflection of the light),

Figure 2A showing a side view of the apparatus and showing its curved region to conform and thus provide a low profile in conjunction with the structural member depicted in Figure 1,

Figure 2B is a view AA of the apparatus of Figure 2A,

Figure 2C is a section at BB of Figure 2A,

Figure 2D is a section at CC of Figure 2A,

Figure 2E is an enlargement of part of the detail of Figure 2E to show the nature of the retention characteristic of the moulded outstand of the light duct,

Figure 2F is a view from below of the member of Figure 2A showing the offsetting of the inlet end for light from the wide but narrow beam producing outlet end,

Figure 3A is a side elevation of the shield member shown in much the same orientation as is the light duct in Figure 2A,

Figure 3B is an end view of the shield of Figure 3A in the direction CC,

Figure 3C is a section of the shield at DD,

Figure 3CC is a larger detailing of the section of Figure 3C,

Figure 3D is a sectional view at EE of the shield of Figure 3A,

Figure 3DD is a larger detailing of Figure 3D,

Figure 3E is a bottom view of the shield of Figure 3A showing the corresponding offset to that of the light duct shown in Figure 2E,

Figure 4A is a pictorial view of attachment apparatus or a clip for (e.g.; push fit) association with the light duct and for engagement by a clip-fit arrangement to the handle or the transition of the handle into the curved region of the structural member,

Figure 4B is a plan view of the attachment apparatus of Figure 4A,

Figure 4C is a view FF of the apparatus of Figure 4B,

Figure 4D is a section at GG of the clip or attachment apparatus of Figure 4C,

Figure 4E is a view HH of the apparatus of Figure 4B,

Figure 4F is a view II of the apparatus of Figure 4B,

Figure 4FF is an enlargement of part of the detail of Figure 4F showing details of the clip fit retention shoulder forming one part of the clipping feature of the attachment apparatus,

Figure 5 shows the relationship of the shield of Figure 3A through 3DD with its associated light duct as shown in Figures 2A through 2E,

Figure 6 is an end view of the arrangement of Figure 5 showing how retention shoulders on either side of the shield are available for attaching the shield and thus assisting in supporting the outlet end of the light duct relative to the structural member (not shown),

Figure 7, in a similar manner to that of Figure 6, shows how, if desired, the protuberant portion of the light duct of Figures 2A through 2E can locate through an opening of the structural member,

Figure 8 shows part of a structural member showing how, if desired, a plurality of different openings can be provided therein at the curved region or immediate region or approaching the distal end so as to allow engagement members such as those down standing

from the shield as shown in Figure 6 to engage without going outside of the shield edges,

Figure 9 shows a view of a structural member having a variety of openings therein for location or engagement purposes,

Figures 10A and 10B show respectively an attachment and detachment of, for example, a clip fit arrangement internally of an opening at or adjacent the transition from the handle into the curved region or intermediate region, the attachment and releasement mechanisms being shown by the arrows,

Figure 11 and Figure 12 show options with respect to some of the openings through the structural member depicted in Figure 9 for location of the shield, and

Figures 13 and 14 are respectively other views demonstrating the relationship that arises from the engagements of Figures 11 and 12 respectively.

COMPONENT LIST: (WHEN INPUT LIGHT IS FROM A LIGHT CABLE):

- RETRACTOR;
  - This could be any retractor, size or shape not critical. Our design as detailed in the drawings is for mini incision and minimally invasive hip replacement.
  - Manufactured from any suitable material i.e. plastic, carbon fibre, stainless steel, titanium.

- LIGHT DUCT;
  - **Clip,** this is the attachment point for the light cable and pipe to retractor. Attachment to the cable is in the form of a screw connection or push lock type. Material could be plastic (e.g.; ABS, Acetyl, polycarbonate, etc.) or metallic. In some situations this feature could be permanently attached to the retractors. Where the shield is utilised to retain the light duct the role of the clip could be reduced to that of attachment interface between the light duct and light cable or may not be required when the cable detail is moulded directly to the pipe. The clip will in some variants provide some or all of the attachment to the retractor through tabs which locate in detail on the surface of the retractor or wrap around the retractor.

  - **Duct,** is moulded from a transparent material (i.e. plastic (i.e.; acrylic, polycarbonate, etc.) or glass) with a high gloss finish over the entire part. Some variants may have a shaped or textured light exit face to change the light pattern

emitting from the duct. It may be provided with an exterior layer or coat that does not cover the inlet or outlet.

- **Shield,** this forms a protective barrier to reduce the chance of damage to the duct from other instruments. It may also improve structural integrity. In some variants this will be optional and may be supplied separately to be placed on the duct during or pre use. The shield attaches to the pipe through detail on the shield which form undercuts or with sprung clipping features. Material can be any durable plastic or a metallic material (ductile or high tensile) [e.g.; stainless steel, spring steel, etc.].

The preferred arrangement with the various engagement options discussed is such that a structural member 1 defines a handle region 2 which has a distal end region 3 linked thereto by a curved region 4 or intermediate region 4 which is of low profile, i.e.; wider than it is thick so that the reduced thickness transversely down through the curved region provides the low profile. Likewise for the liked duct 5 and the shield 6 for regions to substantially conform to at least part of the curved region to the extent required to allow the outlet end 7 of the light duct 5 to direct its beam or beams, as a band, towards the distal end region 3 or the zone of a patients body in proximity thereto.

As will be apparent from the drawings the light member 5 can be provided as the moulded member shown in Figures 2A through 2E as a member that is distinct from engagement apparatus 8 adapted to engage by a thread or other means 9 to the end of a light cable so that the push fitted inlet end of the received light duct (preferably round in section and offset as shown) can take in a high lux beam and offer out as a band (at some reduction in lux) the illuminating beam.

The clamp, clip or the like 8 can of course be integrally moulded with the light tube 5 and have such feature as is apparent from Figures 4A through 4FF as will allow clip fit engagement to the handle 2 of the structural member 1.

Any appropriate clip fit, sliding or permanent fitting of such attachment apparatus 8 can be contemplated and various options for engagement of components together to provide an assembly of a disposable light duct and means for attachment thereof to the structural member at or adjacent the transition of the handle into the curved region can be contemplated. Likewise any association directly or indirectly of other regions of the light duct such as by some measure of location as depicted in Figure 7 as a result of the protuberance shown in

Figure 2DD and an appropriate opening therefore in the structural member as shown in Figure 7.

The present invention is adapted to stabilise the light duct against skewing by appropriate direct or indirect, or both, interactions.

The present invention contemplates situations where the shield can be provided as a separate item (e.g.; supplied with a disposable light duct) or be kept with the structural member 2. Similarly for the member 8.

Disposable light members 5 can be utilised or they can be recycled for use if not damaged.

Any appropriate arrangement whereby there is the assembly, disassembly arrangement contemplated by the earlier statements of the invention are within the scope of the present invention as there are alternative arrangements reliant on such means of inter-engagement which may obviate the need for a shield as a separate item if the light duct itself does not provide concerns as to damage of an exposed surface and can be stabilised using any one or more of the interactions herein depicted of described.

The light duct can sit on the top surface of the structured member. It can be fixed to the structural member through moulded detail on the light duct and clip locking into detail on the structural member. The low profile and close fit provides good visual access.

The light duct alternatively can sit on the top surface of the structural member and be fixed through moulded detail on the light pipe and clip locking into detail on the structural member.

The low profile and close fit provides good visual access.

Reference has been made to the light duct preferably being on the convex side as shown in Figure 1 of the curved region. Other possibilities include its location on the concave side or part of both and, if desired, provision can be made for outlet or outlets from protruding parts of the light duct for the light through openings of the curved region that nonetheless still display light to the same region as will the outlet 7 shown in Figure 1. Multiple outlets for that purpose each from a variety of different poke through parts of a light duct can be contemplated. Such forms however may be less desirable owing to a greater loss of received ducted light.

Preferably the ratio between the light inlet surface area and light outlet surface area is a ratio of no less than 1:1 and no more than 1:11 The current preferred designed ratio is 1:2.2

Preferably the width ratios can be as previously stated.

DATED THIS 7th DAY OF March 2003

AJ PARK

PER

AGENTS FOR THE APPLICANT

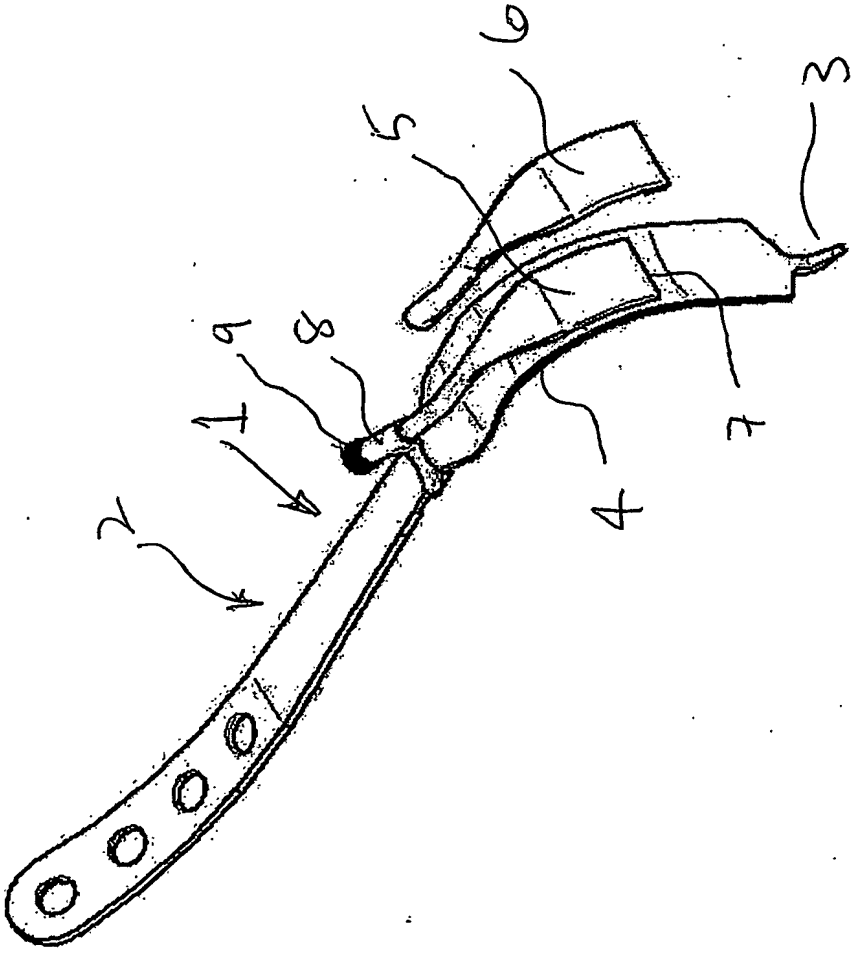

FIG 1

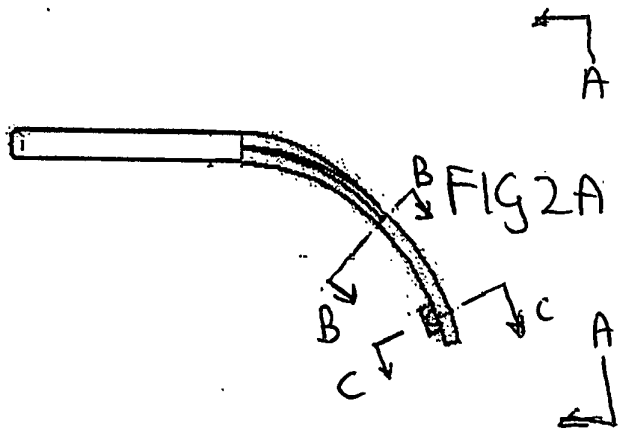

FIG2A

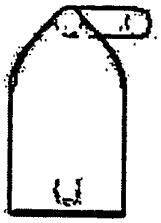

FIG2B

FIG 2DD

FIG2D

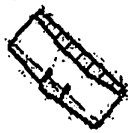

FIG2C

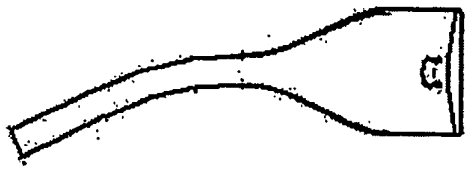

FIG2E

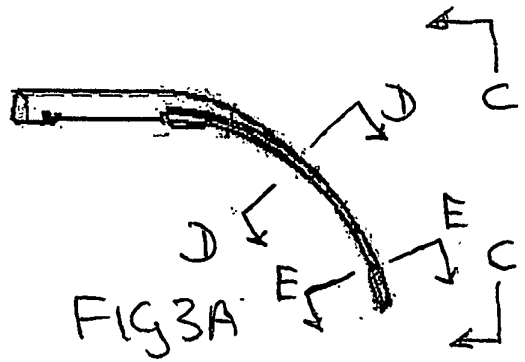

FIG3A

FIG3B

FIG3D

FIG3C

FIG3DD

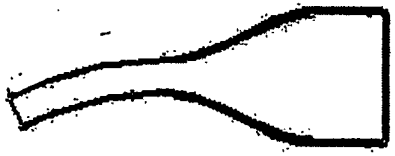

FIG3E

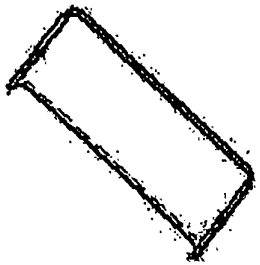

FIG3CC

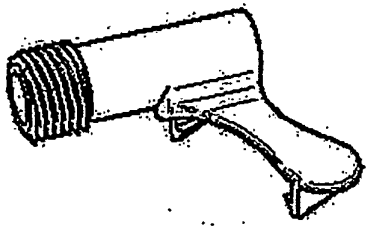

FIG4A

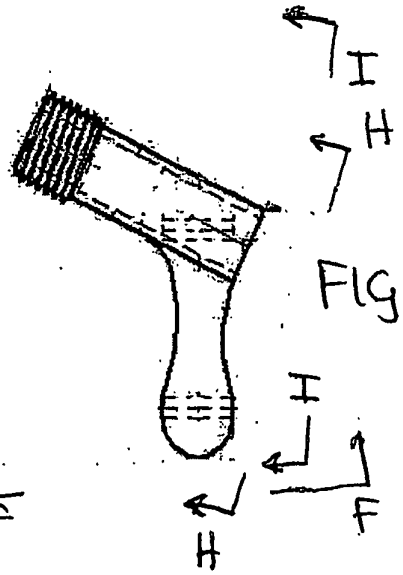

FIG4B

FIG4E

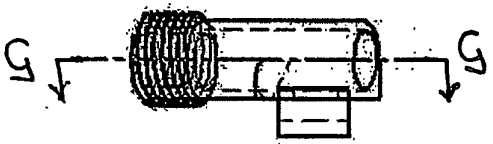

FIG4C

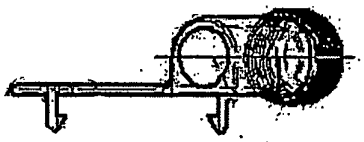

FIG4F

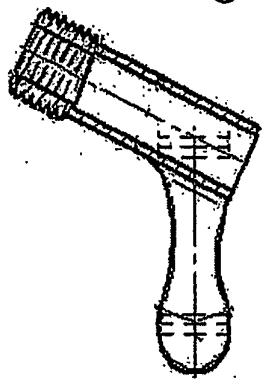

FIG4D

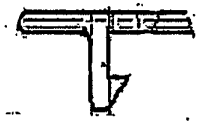

FIG4FF

Fig 10D

Release

Attack

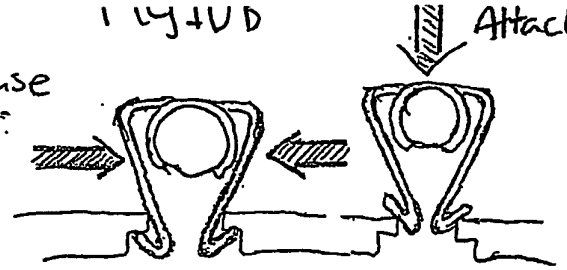

Fig 10A

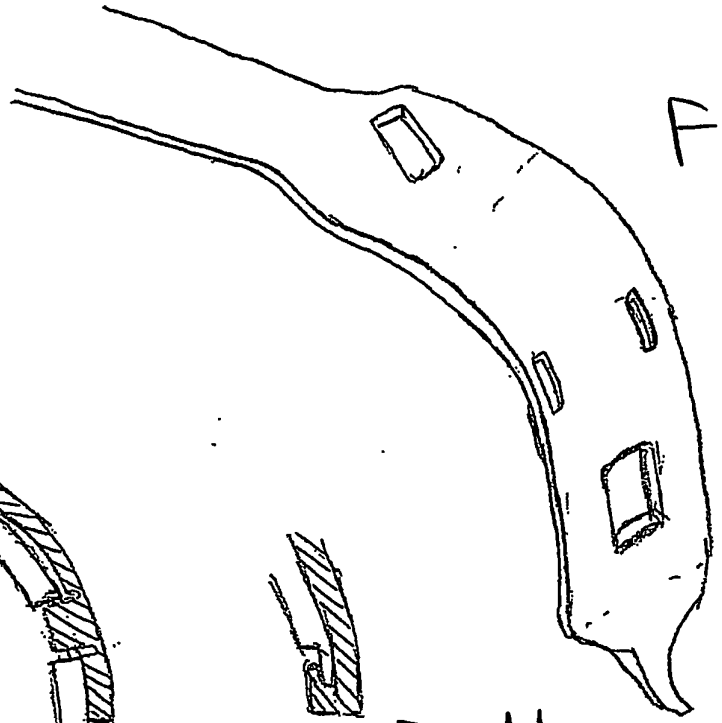

Fig 9

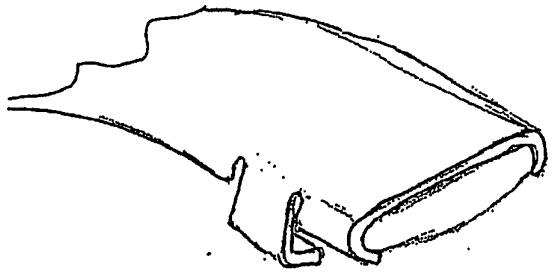

Fig 5

Fig 12

Fig 11

Fig 13

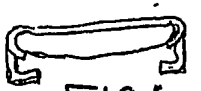

Fig 6

Fig 7

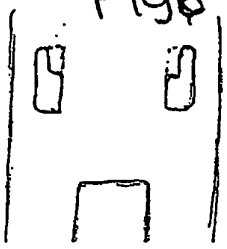

Fig 8

Fig 14

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